UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JAMES TONRA, Ph.D.,	:	
	:	Civil Action No.: 18 Civ. 9028 (JGK)
Plaintiff,	:	
	:	
v.	:	
	:	
KADMON HOLDINGS, INC., HARLAN W. WAKSAL, M.D. and JOHN RYAN, M.D., Ph.D., in their individual and professional capacities,	:	
	:	
Defendants.	:	

MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS

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Plaintiff James Tonra, Ph.D. ("Plaintiff" or "Dr. Tonra") submits this opposition to Defendants Kadmon Holdings, Inc. ("Kadmon" or the "Company"), Harlan Waksal, M.D. and John Ryan, M.D., Ph.D.'s (collectively, "Defendants") motion to dismiss Dr. Tonra's Amended Complaint under Fed. R. Civ. P. 12(b)(6).

PRELIMINARY STATEMENT

On September 27, 2017, Dr. Tonra opposed Defendants' burying new study results showing liver and kidney damage and a lack of efficacy for the drug tesevatinib (aka KD019). He declared to supervisor Dr. John Ryan and at a meeting that the results were legally required to appear in the Investigator's Brochure ("IB"), slated for update in three months, as well as on Informed Consent Forms ("ICFs"). Dr. Tonra believed the Company would not update these documents without his pressing the issue, and that such failure would violate legal reporting obligations, defraud investors, and withhold information of increased risk from doctors and patients. He was right. Kadmon fired Dr. Tonra the very next day (still without any explanation), and belatedly admits that it never updated the IB.

The Amended Complaint's ("AC") allegations fulfill the elements of a Sarbanes-Oxley Act ("SOX") claim. Under Leshinsky and other cases, the purpose and text of SOX contemplate opposition to an imminent violation, an unlawful course it appears a company will take that constitutes a violation of covered laws or rules. Dr. Tonra, a clinical pharmacologist, is not required to know the Securities Exchange Act or federal fraud statutes, but did recognize the Company's intent to secure new investment and protect its valuation without making required public disclosures.

This is not a motion for summary judgment. Defendants cannot present a selective record and make factual assertions to dismiss the claims. Defendants also mischaracterize Plaintiff's protected complaints, attempting to limit Dr. Tonra's opposition to a couple of emails

(in which he does state that the results should be reported publicly and he wants to be directly involved). Discovery is necessary on the emails' context, other verbal and written communications and complaints, additional evidence of retaliatory animus, and the Company's discussion of how the study results would be handled. Defendants' exhibits also reveal that the Company did eschew public reporting of the results and made disingenuous representations to the FDA about the content of the IB (Ex. D, p. 2; Ex. F, p. 2).

Dr. Tonra's Section 740 claim concerns risk to the general public, from which the drug's clinical trial subjects are drawn in numbers that can only be determined through discovery. The Company's new admission regarding failure to update the IB shows that it failed to fulfill legal obligations to inform doctors and patients of new risk data on liver and kidney damage, just as Dr. Tonra feared and tried to prevent.

Defendants ignore that Dr. Tonra's binding employment agreement provides for a "Guaranteed Bonus," and states: "You will receive a guaranteed bonus equal to one third of your annual base salary." Instead, they address only language saying that annual bonuses are "subject to" or may be "adjusted" based upon the performance of Dr. Tonra or the Company. This language does create a dispute as to intent, although it is consistent with providing for higher bonuses, over the one-third salary minimum, for good performance. For this reason, the motion to dismiss is inappropriate, and discovery is necessary on the drafting of the agreement, as well as the parties' intent, practices and discussions.

Finally, Plaintiff's annual one-third salary bonuses were mandatory and non-discretionary under the terms and conditions of his employment (which could only be modified in writing), and so the New York Labor Law ("NYLL") Section 193 claim also must proceed to discovery.

RELEVANT FACTS AND BACKGROUND

I. DR. TONRA'S EMPLOYMENT

Dr. Tonra has 15 years' experience in the pharmaceutical industry and has established himself as a proven asset in transitioning drug candidates from the research phase into clinical testing. See AC ¶¶ 20-22. Kadmon is a biopharmaceutical company engaged in the discovery, development and commercialization of small molecules and biologics.[1] Id. ¶ 1. Since July 2016, Kadmon has been a publicly traded company. Id. ¶ 52. Dr. Waksal was Kadmon's Chief Executive Officer, and Dr. Ryan was Kadmon's Executive Vice President and Chief Medical Officer. Id. ¶¶ 18-19.

In July 2011, Dr. Tonra entered into negotiations to join Kadmon. Id. ¶ 25. On July 25, 2011, Kadmon sent Dr. Tonra a letter containing the parties' final agreement (the "Employment Agreement"). Id. ¶ 26. The Employment Agreement provided for a $232,500 base salary and $20,000 signing bonus. Id. ¶ 27. The Employment Agreement also provided Dr. Tonra a guaranteed annual bonus, stating in relevant part:

> Guaranteed Bonus: [Dr. Tonra] ***will receive*** **a guaranteed bonus equal to one third of [his] annual base salary.** For calendar year 2011, this bonus will be subject to [Dr. Tonra's] performance. Subsequent to 2011, the bonus may be adjusted based on [Dr. Tonra's] performance as well as Company performance. Annual bonuses will be paid no later than March 15th following the year in which they are accrued.

Id. ¶¶ 28-29 (emphasis added). This bonus is not discretionary, as all parties understood that Dr. Tonra was undertaking substantial risk to join Kadmon. Id. ¶ 29. To the extent Dr. Tonra's or the Company's performance could result in an adjustment of the bonus, any such adjustment could only be higher. Id.

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[1] See http://kadmon.com/about-us/ (last accessed March 6, 2019).

In August 2011, Dr. Tonra signed the Employment Agreement and became Kadmon's Vice President of Preclinical Pharmacology. Id. ¶ 30. Dr. Tonra helped advance several projects into clinical testing in the fields of cancer, autoimmune disease, polycystic kidney disease and fibrosis. Id. ¶¶ 31-39. As a result of Dr. Tonra's excellent performance, in November 2015, Kadmon provided Dr. Tonra with a merit-based salary increase from $232,500 to $300,000 and promoted him to Senior Vice President in charge of nonclinical development. Id. ¶ 39. Over the years, but particularly during his last year at Kadmon, Dr. Tonra repeatedly complained to Dr. Waksal regarding the Company's failure to pay him his guaranteed bonuses. Id. ¶¶ 40-44, 53-62.

II. DR. TONRA'S PROTECTED COMPLAINTS REGARDING KADMON'S REPORTING OBLIGATIONS AND HIS MANDATORY BONUSES

A. Kadmon's Reporting Requirements Under Federal Regulations and Law

Before conducting a clinical investigation of a new drug candidate, Kadmon must submit an Investigational New Drug Application ("IND") to the FDA. 21 C.F.R. § 312.20(a). The IND must include a summary of known pharmacological and toxicological effects and a summary of information relating to safety and effectiveness obtained from prior clinical studies. Id. Kadmon must update the IND annually to include any pertinent information learned about the drug. Id. at § 312.33(b). Kadmon must also submit Information Amendments to report "essential information" that had not otherwise been disclosed. Id. at § 312.31(a).

Kadmon must select a qualified investigator to investigate the drug candidate and provide the investigator "with the information they need to conduct an investigation properly," which is disclosed in an Investigator's Brochure ("IB") and includes all information in the IND. Id. at § 312.50, 312.55(a). Kadmon must inform the investigator "of new observations discovered by or reported to the sponsor on the drug, **particularly with respect to adverse effects and safe use**." Id. at § 312.55(b) (emphasis added). The investigator is responsible for, *inter alia*, "protecting

the rights, safety, and welfare of subjects under the investigator's care." Id. at § 312.60. An investigator must obtain the informed consent of human clinical subjects through an Informed Consent Form ("ICF"). Id. Moreover, Kadmon discloses information contained in an IB to investors and potential investors in order to procure funding. Id.

B. Tesevatinib and the PCK Rat Model Study

Kadmon is a sponsor for tesevatinib, one of the Company's top drug candidates, which is currently in human clinical trials, and is being developed as a treatment for patients suffering from Polycystic Kidney Disease ("PKD"). Id. ¶¶ 82-83. In children, PKD is referred to as autosomal recessive polycystic kidney disease ("ARPKD").[2] Id. ¶ 83. PKD causes harmful cysts to form on the kidney and liver. Id. ¶¶ 87-88, 96, 99.

In testing the efficacy and risks of tesevatinib, "PCK rats" are a useful testing subject because they share the same gene mutation present in human ARPKD patients. In early 2017, Dr. Tonra ordered a study of tesevatinib on PCK rats by third-party research lab Crown Bio (the "PCK Rat Model Study" or the "Study"). Id. ¶¶ 83, 86, 89-94. The PCK Rat Model Study was run to determine whether tesevatinib had any determinable negative effects relating to decreased kidney function. Id. ¶¶ 86-88, 94-96. The Study was necessary because a prior study by the Ellis Avener lab found beneficial effects of tesevatinib in PCK rats, but did not determine the blood concentration necessary to achieve efficacy. Id. ¶ 95.

In July 2017, Crown Bio provided Dr. Tonra with unfavorable preliminary data demonstrating an increase in serum creatinine and blood urea nitrogen, both of which indicate an

[2] See http://kadmon.com/press/kadmon-initiates-phase-2-placebo-controlled-clinical-trial-of-tesevatinib-in-autosomal-dominant-polycystic-kidney-disease/ (last accessed on March 5, 2019).

increase in kidney and liver toxicity related to the administration of tesevatinib. Id. ¶¶ 83-88. The results reflected possible shortened life expectancy and an increased likelihood to need organ transplants. Id. The preliminary data also failed to replicate beneficial effects observed in previous studies. Id. ¶ 88. Put simply, the Study not only showed that tesevatinib lacked any benefit in PCK rats, but that it was making the disease worse. Id. ¶¶ 86-88.

C. Dr. Tonra's Disclosure of Initial Negative Results

The same day he learned of the preliminary results, Dr. Tonra informed Dr. Waksal that tesevatinib was not as efficacious as previously believed and actually exacerbated PKD conditions in the PCK rats. Id. ¶ 88. Shortly thereafter, Dr. Ryan came to speak with Dr. Tonra, furious and demanding to know who ordered the Study. Id. ¶ 89. Dr. Tonra acknowledged having ordered the Study, and noted that Dr. Ryan was present and had approved the study. Id. ¶ 90. Dr. Ryan then told Dr. Tonra a story about an employee at his previous company who was terminated after running a nonclinical study that produced negative results. Id. ¶¶ 91-92. Dr. Tonra understood this as a threat to his employment and an indication that Dr. Ryan did not intend to disclose the results of the Study through the appropriate means, despite Kadmon's legal obligations. Id. ¶ 92. Later, while talking just outside of Dr. Tonra's office about the preliminary results, Dr. Ryan ruefully stated "I am going to have to tell people about this," to which Dr. Tonra responded "Yes." Id. ¶ 93.

On or about September 26, 2017, Crown Bio provided Dr. Tonra with the final results of the Study, which confirmed that tesevatinib caused increased kidney and liver toxicity, as well as cyst volume. Id. ¶¶ 94-97. The results also confirmed that the Study was unable to reproduce earlier results showing beneficial effects. Id. ¶ 95. On September 27, 2017, Dr. Tonra emailed the final results of the Study to Dr. Ryan and others. Id. ¶¶ 95-96.

D. Dr. Tonra Insists on Updating Tesevatinib's IB and ICF Immediately After Getting the Final Results

Dr. Tonra also called Kadmon's head of Regulatory Compliance about updating the IB and ICF so physicians, patients, investors and potential investors were on notice of the new information on the negative effects of tesevatinib. Id. ¶¶ 97-99. The head of Regulatory Compliance told Dr. Tonra that there was a meeting that day to discuss the annual update of the IB. Id. ¶ 100. Dr. Tonra specifically asked for the results of the PCK Rat Model Study to be included on the meeting's agenda because he believed that if he did not attend and actively advocate for disclosure of the results, they would not be disclosed, despite Kadmon's reporting obligations. Id. ¶¶ 92, 100, 102.

Dr. Tonra told the meeting attendees that Kadmon was required to update the IB and ICF and disclose the results of the Study, as they showed that tesevatinib posed potential serious health risks to clinical patients. Id. ¶¶ 99-101. Dr. Tonra believed that failing to disclose the results posed a serious risk to public safety and would be tantamount to fraud on investors and potential investors. Id. ¶¶ 102-04. Indeed, Dr. Tonra knew that if the IB and ICF were not updated (even if the IND was), physicians and patients would be unaware of the Study's results and at a disadvantage for identifying potential ongoing negative health effects. Id. ¶ 104. Likewise, as the IB was disseminated to and followed by investors and potential investors, Dr. Tonra believed that failure to disclose and publish the results of the Study would be an omission of material information. Id. ¶¶ 102-03.

E. Dr. Tonra Believed a Violation of Kadmon's Reporting Requirements and Fraud on the Company's Investors Was Imminent

Dr. Tonra ensured that he participated in the annual update meeting and insisted upon the inclusion of the PCK Rat Model Study in the IB update because he believed Kadmon would actively seek to exclude this information, in violation of legal reporting requirements. Id. ¶¶ 92,

102. This belief was based on, *inter alia*, Dr. Ryan's ominous threat regarding an employee who had been terminated for ordering testing that yielded unfavorable data and his dismay at the idea of telling anyone about the Study results, as well as other instances in which the Company made clear that it preferred not to disclose negative information about drug candidates, despite legal obligations. Id. ¶¶ 68, 91-92, 102. For example, in or around August 2016, Dr. Tonra raised concerns regarding Kadmon's development of GLUT3 inhibitors, including that they posed a serious risk of sperm degeneration in test subjects. Id. ¶¶ 65-68. Although Dr. Ryan suggested that Kadmon not update the ICF and IB regarding these risks, it was a nonclinical issue, which fell within Dr. Tonra's purview, and Dr. Tonra insisted that the ICF and IB were updated as required. Id. ¶ 68.

Dr. Tonra also reported health risks related to the development of Rho-kinase inhibitors, including serious risks of hypertension or low blood pressure, and advised that the Company cease developing those drug candidates. Id. ¶¶ 69-70. Rather than take Dr. Tonra's concerns seriously, Kadmon ignored Dr. Tonra and retaliated against him by excluding him from research project meetings. Id. ¶ 71.

III. KADMON IMMEDIATELY TERMINATES DR. TONRA, IN TRANSPARENT RETALIATION FOR HIS INSISTENCE THAT KADMON REPORT ADVERSE RESULTS

On September 28, 2017, the day after Dr. Tonra disclosed the results of the Study, Kadmon fired Dr. Tonra. Id. ¶ 106. Defendants have not offered any explanation for this, and do not dispute that Dr. Tonra's termination was related to his complaints concerning the need to disclose the PCK Rat Model Study.

A few weeks later, Dr. Waksal stated publically that:

> Tesevatinib has been shown to inhibit molecular pathways central to the progression of PKD—mediated by its inhibition of the epidermal growth factor

> receptor (EGFR) and Src family kinases—and also accumulates in the kidneys, making it **a promising therapeutic candidate** for this disease.

Id. ¶¶ 107-08 (emphasis added). Dr. Waksal did not disclose the fact that the PCK Rat Model Study called into question the efficacy of tesevatinib and showed negative effects, and Kadmon also never updated the IB regarding the results of the Study. Id. ¶¶ 107-18. Indeed, Kadmon now admits that, despite the direct evidence that tesevatinib resulted in increased toxicity in the liver and kidneys and increased cyst volume, it has not updated the IB at any time since Dr. Tonra's termination in September 2017.[3] See Defs.' Mem. at 9 n.7.

LEGAL ARGUMENT

I. MOTION TO DISMISS STANDARD REQUIRES DISCOVERY

To survive a motion to dismiss, the plaintiff must allege "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). The court "must accept all allegations in the complaint as true and draw all inferences in the non-moving party's favor." U.S. ex rel. Siegel v. Roche Diagnostics Corp.,

[3] Although Kadmon asserts that it submitted an Information Amendment regarding the Study to the FDA pursuant to 21 C.F.R. § 312.31 (a document that would not be distributed to investors, doctors or patients), these and many other facts Defendants cite are not alleged in the Amended Complaint, and are not properly considered in deciding Defendants' motion. Even accepting that Defendants submitted an Information Amendment, it does not affect the fact that Defendants belatedly concede (after contending otherwise to the Court) that they did not update the IB to include the results of the Study, as directed by Dr. Tonra in his complaint to the Company. See Defs.' Mem. at 9 n.7. This reversal alone underscores the need for discovery on Plaintiff's SOX and Section 740 retaliation claims.

988 F. Supp. 2d 341, 343 (E.D.N.Y. 2013). The court's consideration is "limited to the complaint and documents attached thereto." NorGuard Ins. Co. v. Lopez, No. 15 Civ. 5032 (DRH)(AYS), 2017 WL 354209, at *5 (E.D.N.Y. Jan. 24, 2017). Courts regularly disregard extrinsic material submitted in support of a motion to dismiss. See, e.g., Tommy Lee Handbags Mfg. Ltd. v. 1948 Corp., 971 F. Supp. 2d 368, 382 (S.D.N.Y. 2013) (disregarding extrinsic evidence and considering only "the complaint and any documents incorporated therein").

Defendants selectively rely upon voluminous extraneous information, including emails between Dr. Tonra and others at Kadmon (without the benefit of any related testimony or other documents), and submissions Kadmon made to the FDA (but no updated IB). See Defs.' Exs. A-F. These documents are not attached to the Amended Complaint or incorporated by reference therein, and Defendants attempt to fabricate their own unilateral pre-discovery record that purports to show that they made required disclosures. The Court should disregard these extraneous materials. See Tommy Lee Handbags Mfg. Ltd., 971 F. Supp. 2d at 382.

II. KADMON PROMPTLY TERMINATED DR. TONRA AFTER HE COMPLAINED ABOUT IMMINENT VIOLATIONS OF LEGAL REPORTING REQUIREMENTS COVERED BY SOX

A. SOX Claim Elements

To state a whistleblower retaliation claim under the Sarbanes-Oxley Act, a plaintiff must allege "that (1) he engaged in protected activity; (2) the employer knew of the protected activity; (3) he suffered an unfavorable personnel action; and (4) circumstances exist to suggest that the protected activity was a contributing factor to the unfavorable action." O'Mahoney v. Accenture Ltd., 537 F. Supp. 2d 506, 510 (S.D.N.Y. 2008); see also 18 U.S.C. § 1514A(a). It is well-established "that courts should construe Section 806 broadly." Leshinsky v. Telvent GIT, S.A., 942 F. Supp. 2d 432, 440 (S.D.N.Y. 2013). Defendants only assert that Dr. Tonra did not make a protected complaint. See Defs.' Mem. at 12-17.

B. Dr. Tonra Complained of the Legal Obligation to Report Results That He Believed the Company Would Bury in Violation of Kadmon's Reporting Obligations, in a Fraud on Investors and Others

A complaint is protected under SOX if the plaintiff "(1) provides information, (2) regarding any conduct which the employee reasonably believes constitutes a violation of . . . any rule or regulation of the Securities and Exchange Commission, or any provision of Federal law relating to fraud against shareholders, to (3) a federal agency, Congress or a person with supervisory authority over the employee." Leshinsky, 942 F. Supp. 2d at 441-42 (quoting 18 U.S.C. § 1514A(a)(1)).

A whistleblower need not wait until an actual violation of applicable law occurs for his complaint to be protected under SOX. Rather, a complaint is protected if it concerns conduct that, if seen through, would constitute a violation. See Leshinsky, 942 F. Supp. 2d at 446 ("[I]mminent crimes, or at least crimes in their infancy, are within the scope of Section 806."); Murray v. UBS Sec. LLC, No. 14 Civ. 927 (KPF), 2017 WL 1498051, at *10 (S.D.N.Y. Apr. 25, 2017) (holding conduct the plaintiff believed to be illegal but that had not yet actually occurred stated a claim). Courts have observed that requiring waiting until an actual violation occurs would defeat the purpose of SOX. See, e.g., Leshinsky, 942 F. Supp. 2d at 446 ("[I]t would frustrate the purpose of Sarbanes-Oxley to require an employee, who knows that a violation is imminent, to wait for the actual violation to occur when an earlier report possibly could have prevented it."); Murray, 2017 WL 1498051, at *10 (rejecting argument that "employees . . . are unprotected by the statute unless they actually capitulate to inappropriate influence"); see also Wiest v. Lynch, 710 F.3d 121, 133 (3d Cir. 2013) (same observation as Leshinsky).

Dr. Tonra was not required to wait until Kadmon failed to disclose the results of the PCK Rat Model Study for his complaint to be protected. He opposed what he reasonably believed was Kadmon planning to engage in conduct that violated its reporting requirements by failing to

disclose the results of the Study in the upcoming update to the IB and ICF, thereby omitting relevant information to investors and potential investors. AC ¶¶ 92, 99-104. Indeed, Kadmon concedes (in a footnote) that it **did not** update its IB in 2018 and has not done so since Dr. Tonra's termination. Defs.' Mem. at 9 n.7. Contrary to Defendants' assertion that they were not required to disclose the Study "under any regulation," Kadmon was required to "keep each participating investigator informed of new observations discovered by or reported to the sponsor on the drug, **particularly with respect to adverse effects and safe use**." 21 C.F.R. § 312.55(b) (emphasis added); see also 21 C.F.R. § 312.50 (sponsors are responsible for "ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects or risks").

Defendants' assertion that they submitted the Study to the FDA as an information amendment to the IND only further demonstrates that they knew the results of the Study were relevant and necessary to disclose, as 21 C.F.R. § 312.23(a)(8) provides that "the sponsor is required to submit informational amendments, as appropriate, with additional information pertinent to safety." These are effectively the same circumstances under which an IB must be updated, and there is no basis for Kadmon to have submitted the information amendment to the FDA, while simultaneously claiming it was not obligated to update the IB.[4] Kadmon's admitted failure to update the IB is a violation of its reporting obligations.

Furthermore, Defendants' May 2018 annual update to the IND contains a material misrepresentation, as it states that findings of REDACTED REDACTED and that REDACTED

[4] The information amendment and its related documents are not referenced in the Amended Complaint and are not properly considered in deciding the instant motion.

REDACTED Defs.' Ex. F. However, Defendants now concede they did ***not*** update the IB to include the PCK Rat Model Study and any prior disclosures did not incorporate the newly available information concerning heightened risk and lack of efficacy associated with tesevatinib. Therefore, Kadmon's representation concerning the contents of the IB was misleading at best.

Discovery also is necessary to determine why Kadmon waited **months** to disclose the results of the Study in an information amendment and did not update the IB, when it already had the final results of the study on September 27, 2017. To that end, Dr. Tonra believed that the final report would be ready well in advance of an annual update to the IB (which Kadmon did as a matter of course in January), and discovery may demonstrate a purposeful delay by the Company in order to delay or avoid disclosure of the Study. Indeed, after receipt of the final results of the study, Kadmon sought to disclose the results to Ellis Avener to "get their take on this" (Defs.' Ex. B), potentially delaying completion of a final report. The need for discovery concerning the impetus for any delay is high in light of Dr. Tonra's allegations that Kadmon was in the process of seeking additional funding, and Dr. Waksal made public statements in late 2017 touting the efficacy of tesevatinib while omitting the findings of the Study. See AC ¶¶ 85,107-08.

In their motion, Defendants misconstrue the nature of Dr. Tonra's complaints and cherry-pick emails in a procedurally inappropriate attempt to demonstrate that Dr. Tonra did not believe that there was a need to report the results of the Study. According to Defendants, "Tonra's SOX claim rests on the contention that he engaged in a 'protected activity' by 'communicating the final results of the tesevatinib' Rat Study to Kadmon." Defs.' Mem. at 13. Dr. Tonra did not merely *convey* the results of the Study to Defendants. Rather, he complained that Defendants

were required to report the results of the Study to the appropriate regulators, and believed that there was a significant likelihood that they would not do so (since borne out). See AC ¶¶ 92, 99-104. Indeed, Dr. Tonra's complaint proved to be correct, as Defendants concede they did not update the IB to reflect the results of the Study. Supra at 12.

Contrary to Defendants' argument that Dr. Tonra's complaints did not concern a violation of any securities law, SEC Rule 10b-5 prohibits any act or omission resulting in fraud or deceit in connection with the purchase or sale of any security. 17 C.F.R. § 240.10b-5(b); see also 15 U.S.C. § 78j(b) (prohibiting the use of "any manipulative or deceptive device or contrivance in contravention" of SEC rules). The relevant inquiry in determining whether a violation of SEC Rule 10b-5 has occurred is "whether a reasonable investor would have viewed the nondisclosed information as having significantly altered the total mix of information made available." Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011). The issue of materiality is a "fact intensive inquiry" and "summary adjudication of a Rule 10b-5 claim is not appropriate on the ground that the alleged misstatements or omissions were not material unless they would have been so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." Rizzo v. McManus Grp., Inc., 158 F. Supp. 2d 297, 303 (S.D.N.Y. 2001).

Dr. Tonra specifically alleges that "information from the Investigator's Brochures reaches the Company's investors and potential investors, including through their distribution by Kadmon management." AC ¶ 98. He further alleges that "[o]ne of Kadmon's key investors has a close family member who suffers from ARKPD, providing Kadmon with an added incentive to ensure and protect the appearance of tesevatinib's progress and success." Id. ¶ 84. Finally, he

alleges that, because Kadmon was in the process of seeking an additional round of funding following its IPO, "progress on tesevatinib's continued deployment was vital." Id. ¶ 85.

A failure to report the results of the Study would result in the dissemination of materially incomplete and misleading information concerning a drug candidate in human testing, and Dr. Tonra's complaints concerned a violation of the securities laws. See Matrixx Initiatives, Inc., 563 U.S. at 44 (holding that an omission was material when the defendant alleged a causal relation between a drug and specific negative effect); In re Sanofi-Aventis Sec. Litig., 774 F. Supp. 2d 549, 565 (S.D.N.Y. 2011) (holding that an omission that "may have provided a more complete picture of [a drug candidate's] approval status" was material). Notably, the FDA clearly viewed the results of the Study to be relevant and worthy of further inquiry, as it sought additional information from Kadmon after submission of the information amendment. Defs.' Ex. E. The additional information that Kadmon provided was obviously not included as an update to the IB. At a minimum, the extent to which the conduct about which Dr. Tonra complained would be deemed "material" for purposes of SEC Rule 10b-5 is an issue ripe for discovery. See Matrixx Initiatives, Inc., 563 U.S. at 44; Rizzo, 158 F. Supp. 2d at 303.

Contrary to Defendants' assertion that Dr. Tonra did not subjectively or objectively believe that a violation had occurred, Dr. Tonra did believe, objectively and subjectively, that Defendants violated, or intended to violate, securities laws by failing to disclose the results of the Study. Dr. Tonra's good faith belief is supported by the fact that he was confronted with dismay and anger regarding the prospective need to report when the preliminary results regarding tesevatinib's harmful effects first came out in July 2017. AC ¶¶ 89-93. Likewise, Dr. Tonra had not been included on a meeting notice regarding the IB update, but he learned about the meeting and made sure that he attended it on September 27, 2017. Id. ¶ 100. Dr. Tonra's exclusion,

particularly after he had previously conveyed the preliminary results, which Dr. Ryan was dismayed at possibly having to report, further demonstrates that Defendants sought to avoid input from Dr. Tonra regarding the Company's need to report the Study's results.

When Crown Bio provided Dr. Tonra with the final results of the Study in late September 2017, Dr. Tonra immediately and repeatedly reminded Kadmon's executive management that the results had to appear in the publicly issued IB (for January 2018), and on which work would have to be started quickly in order to complete it (hence the September 27, 2017 meeting). Id. ¶¶ 94-104. He made this clear to Dr. Ryan on September 27, 2017, along with his belief that to do so would constitute a violation of applicable rules (which, as explained, also implicate fraud on the Company's shareholders and investors, not to mention doctors and patients, and violation of various SEC rules and laws applicable to public companies). Id. ¶¶ 94, 100-03. Dr. Tonra ultimately learned of and attended the IB update meeting, at which he made clear that the finalized results for tesevatinib must appear in the IB's next update under applicable requirements, and that the new results were significant from a risk disclosure standpoint. Id. ¶¶ 100-04. Indeed, Defendants' concession that they failed to update the IB concerning the PCK Rat Model Study conclusively establishes the reasonableness and sincerity of Dr. Tonra's concerns and complaints.

These facts are more than sufficient at this stage of the proceedings to demonstrate that Dr. Tonra possessed an objectively and subjectively reasonable belief that Defendants would fail to disclose the contents of the Study, and that such a failure to disclose would be a violation of relevant securities laws. Pardy v. Gray, No. 07 Civ. 6324 (LAP), 2008 WL 2756331, at *5 (S.D.N.Y. July 15, 2008) (observing that a reasonable belief may be based on available information, personal knowledge, and applicable training); see also Perez v. Progenics

Pharmaceuticals, Inc., 965 F. Supp. 2d 353, 365 (S.D.N.Y. 2013) (observing that a lack of training in securities law could support an inference that the plaintiff reasonably believe that conduct violated the relevant laws).

III. DEFENDANTS FAILED TO DISCLOSE A THREAT TO PUBLIC HEALTH, IN VIOLATION OF N.Y.L.L. § 740

N.Y.L.L. § 740 prohibits retaliation against an employee who "discloses, or threatens to disclose to a supervisor or a public body an activity, policy or practice of the employer that is in violation of the law, rule or regulation which violation creates and presents a substantial and specific danger to the public health or safety." N.Y.L.L. § 740(2)(a). At the pleading stage, "the complaint need not specify the actual law, rule or regulation violated" as long as it "identif[ies] the particular activities, policies or practices in which the employer allegedly engaged." Webb-Weber v. Cmty. Action for Human Servs., Inc., 23 N.Y.3d 448, 453 (2014).

Dr. Tonra believed that Defendants were going to threaten public health and safety by violating their reporting requirements regarding the PCK Rat Model Study. Id. ¶¶ 82-83, 87-93, 102-104. As discussed above, Dr. Tonra's belief was both subjectively and objectively reasonable, as Defendants' conduct made clear that there was a substantial likelihood that the negative results of the PCK Rat Model Study would not be reported as required. Supra at pp. 14-16. As tesevatinib was in human clinical testing, with the ultimate intention being to sell the drug to the public, Dr. Tonra's complaints were related to a violation that created a substantial and specific danger to the public health or safety. See Underwood v. Roswell Park Cancer Inst., No. 15 Civ. 684 (FPG), 2017 WL 131740, at *19 (W.D.N.Y. Jan. 13, 2017) (holding that the plaintiff stated a claim under N.Y.L.L. § 740 where physicians failed to report certain complications and patient deaths); Webb-Weber, 23 N.Y.3d at 453 (holding that allegations that the defendant falsified patient medication and treatment records were sufficient to state a claim

under N.Y.L.L. § 740). Indeed, as discussed above, the FDA viewed the results as significant, as they asked for follow-up information following submission of the information amendment.

Defendants assert that Dr. Tonra "did not object to or raise any internal complaints about anything." Defs.' Mem. at 18. However, Dr. Tonra specifically complained that Defendants were required to disclosure of the results of the Study and opposed pushback on reporting them. AC ¶¶ 99-104. As discussed above, Dr. Tonra's complaints were based on his reasonable belief that Defendants would fail to disclose the results, thereby causing a threat to public health and safety. Supra at pp. 14-16.

Furthermore, Defendants' assertion that Dr. Tonra's complaints did not concern conduct that created any substantial and specific risk to public health or safety is meritless. Defs.' Mem. at 18. Dr. Tonra complained about drugs that were actively being tested on people, and for which clinical tests remain ongoing to this day.[5] See AC ¶¶ 82-83. The ultimate purpose of the clinical testing is to eventually market and sell tesevatinib to the public. The mere fact that participants in the clinical testing executed (non-updated) ICFs does not change the fact that the information learned from the Study was relevant and necessary to be disclosed to participants. Indeed, in the emails that Defendants submit in support of their motion, Dr. Tonra repeatedly references updating the IB and ICF, as it was vital that the investigators and physicians administering the clinical trials, as well as individuals participating in the trials, be aware of the Study. Defs.' Exs. B-C. Likewise, Defendants' assertion that "the safety risks reported in the Rat Study were already known and disclosed to the FDA" is disingenuous. See Defs.' Mem. at 18. The Study had obviously not been previously disclosed (certainly not in the IB for physicians), and the newly received test results are strongly related to a danger to public health.

[5] See https://clinicaltrials.gov/ct2/show/NCT03203642 (last accessed March 6, 2019).

Defendants' case law is readily distinguishable. For example, in Kern v. DePaul Mental Health Servs., the court found no threat of public harm based on alleged neglect of a **single patient**. 152 A.D.2d 957, 958 (1989). Likewise, in Lloyd v. Cardiology & Internal Med. of Long Island, PLLC, 16 Misc.3d 1129(A) (N.Y. Sup. Ct. Aug. 23, 2007), the court held that violations of practicing health care beyond the authorized scope and "preparation of a writing in connection with workers' compensation insurance" in **two instances** were insufficient to establish a threat to the public health. In contrast, Dr. Tonra complained about a drug that is being distributed to many testing patients, on a continuing and ongoing basis, with the ultimate intention of being sold to the public at large. AC ¶¶ 82-83, 88, 99-104. This is not a closed-ended, one-off event, and the failure to disclose negative or unfavorable Study results poses a legitimate and immediate risk to the public. Therefore, Dr. Tonra's complaints were protected under N.Y.L.L. § 740.

Dr. Tonra's allegations support an inference that the public safety is at risk by a failure to disclose the adverse results of the PCK Rat Model Study to hospitals, doctors, patients and test participants. Discovery is necessary to determine the number of participants in clinical testing (drawn from the general public) and the imminence of selling tesevatinib. Defendants' motion to dismiss Dr. Tonra's N.Y.L.L. § 740 claim should be denied.

IV. DR. TONRA'S DISPUTED BONUSES WERE MANDATORY, NOT DISCRETIONARY, AND DISCOVERY IS NECESSARY DESPITE KADMON'S ASSERTIONS

A. Breach of Contract

To state a claim for breach of contract, the plaintiff must allege "(1) the existence of a contract between itself and the defendant, (2) performance of the plaintiff's obligations under the contract, (3) breach of the contract by that defendant, and (4) damages to the plaintiff caused by that defendant's breach." Diesel Props S.r.l. v. Greystone Bus. Credit II LLC, 631 F.3d 42, 52

(2d Cir. 2011). Agreements must be "construed in accord with the parties' intent, as expressed in the unequivocal language they have employed." Levion v. Societe Generale, 822 F. Supp. 2d 390, 397 (S.D.N.Y. 2011). Where a contract is ambiguous, the court should deny a motion to dismiss and allow for discovery concerning the parties' intent. Neopharm Ltd. v. Wyeth-Ayerst Int'l LLC, 170 F. Supp. 3d 612, 615 (S.D.N.Y. 2016) (holding that, if a contract is ambiguous, "the Court must examine extrinsic evidence of the parties' intent . . . and proceed to discovery").

There is no dispute that Dr. Tonra's Employment Agreement created a binding contract between Dr. Tonra and Kadmon and that Dr. Tonra performed his obligations under the agreement. The Employment Agreement explicitly provides that Dr. Tonra will receive a **guaranteed bonus** of one-third of his annual salary, which Defendants failed to pay. AC ¶¶ 28-29; see also Defs.' Ex. A. To the extent the Employment Agreement allows for adjustment to the bonus, Dr. Tonra alleges, and a reasonable reading of the agreement supports, that any such adjustment can only be upward, as he was guaranteed a baseline bonus of one-third of his salary. Id. ¶ 29.

Defendants assert that the agreement "is clear that the bonuses at issue are discretionary," and that Kadmon "retained discretion over the amount of bonus compensation to be awarded." Defs.' Mem. at 21. However, an interpretation of the Employment Agreement in which Dr. Tonra's bonus could be adjusted downward at Kadmon's discretion would render the word "guaranteed" meaningless, which is an impermissible interpretation under New York law. Fifth Ave. Exec. Staffing v. Virtual Cmtys., Inc., No. 01-372, 2002 WL 398512, at *1 (1st Dep't Feb. 28, 2002) ("A contract should be construed so as to give full meaning and effect to all of its provisions; words and phrases are to be accorded their plain meaning."). The only reasonable

interpretation that gives meaning to all words, and the parties' clear intent, is that any discretion was limited to an upward adjustment of the guaranteed bonus.

Defendants' case law is again distinguishable. In Arrouet v. Brown Bros. Harriman & Co., No. 02 Civ. 9061 (TPG), 2005 WL 646111, at *4 (S.D.N.Y. Mar. 18, 2005), the court held that a discretionary bonus was insufficient to support a breach of contract claim where the plaintiff "conceded that his supervisors possessed the discretion to reduce his end-of-year compensation based on his behavior." Likewise, in Namad v. Salomon Inc., 74 N.Y.2d 751, 753 (1989), the Court of Appeals found a bonus insufficient to form the basis for a breach of contract claim where a company had unambiguous discretion in setting the bonus, and the plaintiff asserted he was entitled to the bonus based on "customary policy." In contrast to Arrouet and Namad, Dr. Tonra alleges that he was **guaranteed** a bonus of at least one-third of his salary, which could only be adjusted upward, and not downward. AC ¶¶ 28-29.

At the very least, discovery is appropriate to determine the parties' intent regarding the issue of the guaranteed bonus. Although the wording of the Employment Agreement clearly demonstrates that Dr. Tonra's bonus was guaranteed, discovery is appropriate with respect to the issue of intent and the ability to adjust the bonus. US Oncology, Inc. v. Wilmington Tr. FSB, 102 A.D.3d 401, 402 (1st Dep't 2013) (allowing for discovery where a contract was susceptible to multiple interpretations). Therefore, Defendants' motion to dismiss Dr. Tonra's claim for breach of contract should be denied.

B. Breach of the Implied Covenant of Good Faith

In moving to dismiss Dr. Tonra's claim for breach of the implied covenant, Defendants simply argue that where such claims "are pled based on the same facts, the latter is duplicative and subject to dismissal." Defs.' Mem. at 22. However, claims for breach of contract and

breach of the implied covenant of good faith may be pled in the alternative. Fantozzi v. Axsys Techs, Inc., No. 07 Civ. 2667 (LMM), 2008 WL 4866054, at *7-8 (S.D.N.Y. Nov. 6, 2008) (holding that claims for breach of contract and breach of the implied covenant may be brought in the alternative). Therefore, Defendants' motion to dismiss Dr. Tonra's claim for breach of the implied covenant should be denied.

C. N.Y.L.L. § 193

N.Y.L.L. § 193 prohibits an employer from making wage deductions unless permitted by law or authorized by the employee for certain payments for the employee's benefit. N.Y.L.L. § 193(1)(a). A guaranteed, non-discretionary bonus is considered "wages" for purposes of N.Y.L.L. § 193. Ryan v. Kellog Partners Institutional Servs., 19 N.Y.3d 1, 16 (2012) (a bonus was a wage where it "had been earned and was vested").

Dr. Tonra's right to receive a bonus was mandatory, not discretionary, as he was guaranteed at least a bonus of one-third of his salary. AC ¶¶ 28-29. Although the Company could, in its discretion, *increase* the amount of Dr. Tonra's bonus, he was guaranteed a minimum of one-third of his salary. Id. By failing to pay Dr. Tonra his contractually guaranteed bonus, the Company unlawfully withheld wages in violation of N.Y.L.L. § 193. Esmilla v. Cosmopolitan Club, 936 F. Supp. 2d 229, 256 (S.D.N.Y. 2013) (denying summary judgment where a question of fact existed regarding whether a bonus was guaranteed). Defendants' contractual arguments, which glaringly fail to discuss the relevant language in full, merely illustrate the necessity of discovery.

CONCLUSION

Defendants' motion to dismiss should be denied due to the many factual issues on which discovery is necessary (including regarding Plaintiff's protected activity) and the obviously retaliatory nature of the termination of Dr. Tonra.

Dated: March 6, 2019
New York, New York

Respectfully submitted,

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By: _____

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CERTIFICATION PURSUANT TO HON. JOHN G. KOELTL'S INDIVIDUAL PRACTICE RULE 2(D)

In accordance with Hon John G. Koeltl's Individual Practice Rule 2(D), I hereby certify that this Memorandum of Law in Opposition to Defendants' Motion to Dismiss Plaintiff's Amended Complaint contains 6,989 words, including footnotes, but excluding the caption, tables, counsel's signature block, and this certification, as counted by Microsoft Word, and that the Memorandum complies with Local Civil Rule 11.1 of the Southern District of New York and the Court's Individual Rules of Practice.

Dated: March 6, 2019

By: _____
Lawrence M. Pearson